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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,459	05/08/2000	Artur Mitterer	BHV-305.01	4372

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[REDACTED] EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	15

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/367,459</b>	Applicant(s) <b>Mitterer et al.</b>
Examiner <b>Hope Robinson</b>	Art Unit <b>1653</b>

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Feb 19, 2002.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 17-37 is/are pending in the application.

4a) Of the above, claim(s) 26-37 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 17-25 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. PCT/AT98/00043.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8, 13

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

1. Applicant's election without traverse of Group I (claims 17-25) in Paper No. 14 is acknowledged.

### ***Specification***

2. The specification is objected to because of the following informalities:

The specification is objected to because the priority information is not disclosed on the first page of the specification. On page 11 of the specification, line 13 reads "i.a." which appears to be an error. In addition the specification is objected to because of the arrangement as no headings are listed. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.

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1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.  
(g) Brief Description of the Several Views of the Drawing(s).  
(h) Detailed Description of the Invention.  
(i) Claim or Claims (commencing on a separate sheet).  
(j) Abstract of the Disclosure (commencing on a separate sheet).  
(k) Drawings.  
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Correction is required.

*Abstract*

3. The abstract is objected to because this application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).

An abstract on a separate sheet is required.

*Information Disclosure Statement*

4. The information disclosure statement filed on May 8, 2000 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement were not translated. It has been placed in the application file, but the

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information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: AI, AK, AL, AM, AN and AO.

***Basis For NonStatutory Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 17-25 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-40 of copending Application No. 09/367,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a method of recovering vWF/factor VIII/vWF complex. The copending application recites a method of recovering vWF comprising a low salt concentration and binding vWF to a cation exchanger. The method also involves elution and recovery of purified vWF. The present application recites a method of recovering factor VII/vWF-complex by using a cation exchanger and a step wise elution process. Both applications disclose similar method steps although the scope of the claims are different. Therefore, the disclosure in the copending application makes obvious the claimed invention in the instant application. Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions since the language in the claim is similar. Thus, the instant application claim is an obvious variation of the copending application claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 and the dependent claims hereto are indefinite for the recitation of “particularly containing”, as this term does not clearly convey the claimed invention. It is suggested that the term “particularly” be deleted from the claim. See also claim 21 which recites “particularly free”. The claim is further indefinite for the recitation of the acronym “factor VIII/vWF-complex” without the spelled out meaning, as the acronym alone is not sufficient to convey the claimed invention.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Arrighi et al. (EP 600480, December 2, 1993).

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The claimed invention is directed to a method for recovering factor VIII/vWF-complex comprising a cation exchanger, step-wise elution process wherein the complex is bound to said cation exchanger at a salt concentration of  $\leq$  250 mM (see claims 17-25). Arrighi disclose a process for the extraction of factor VIII-von Willebrand Factor complex from total plasma wherein the FVIII:C-vWF- complex is eluted from the column under suitable saline and pH conditions, after suitable stabilization, treatment with aluminum hydroxyde and viral inactivation is further purified by a cationic exchanger. In addition, the process disclosed by Arrighi enables obtaining a FVIII:C-FvWF with high purity (specific activity and yield), by adsorbing the FVIII directly from the total plasma. Additionally, Arrighi discloses a process that uses a saline solution containing 0.1-0.15M sodium chloride pH 7.5-8.5 (preferably pH 8) which is added to stabilize and predilute plasma (see abstract and columns 1-2). Thus the Arrighi reference anticipates the claims.

*Art of Record*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fischer et al. (EP 705846, October 4, 1996). Fischer disclose an affinity chromatography method for separating the high and low molecular weight forms of vWF. Fischer also disclose

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that there method is a useful diagnostic tool and can be used in pharmaceuticals. Fischer further discloses the fractionation of vWF by elution from a column of heparin toyopearl with a salt gradient (see abstract). Fischer do not expressly teach the use of a cationic exchanger.

Kumar et al. (EP 295,645, June 15, 1988). Kumar teaches methods for purifying factor VIII:C, von Willebrand factor (vWF) or complexes thereof, however, does not teach the use of a cationic exchanger.

***Conclusion***

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:00 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's

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name on a cover sheet attached to your communication should you choose to fax your response.

The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS  
*HP*

Patent Examiner

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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